

Attorney Docket No.: 6809.230-US  
Filed: January 30, 2004  
Via Facsimile No.: 571-273-8300

Application Serial No.: 10/768,371  
Inventors: Igor Gonda et al.

## REMARKS

Claims 1-25 have been cancelled. New claims 26-31 are now pending.

### Arguments Applicable to all Pending Claims

Applicants' pending claims are directed toward a method of treating diabetes. According to the claimed methods, diabetics who lack the ability, *absent medical treatment*, to maintain an adequate blood sugar level, can achieve acceptable blood glucose levels by inhaling powdered insulin. Applicants note that the claims require that the diabetic lack sufficient ability to produce insulin on his own in quantities necessary to regulate blood sugar levels and that the inhalation of powdered insulin results in the regulation of blood sugar levels to an acceptable levels. To be an effective treatment, the claims further require that the insulin be absorbed in a repeatable and controlled manner and not merely be inhaled in controlled and repeatable quantities. These features are necessary for inhaled powdered insulin to be a useful treatment for diabetics.

In the previous office actions, the Examiner has asserted that the previously pending claims were obvious in view of Laube and Weiner. According to the Examiner, Laube discloses inhaling liquid insulin and Weiner discloses inhalation of powdered insulin. Assuming, without conceding that the Examiner has correctly characterized Laube, the rejection is not applicable to the present claims, because the totality of the references teach away from the claimed invention.

It is well-settled patent law that if the art teaches away from the claimed invention, then the claimed invention is not obvious. See MPEP 2141.02, 2145, WL Gore and Associates Inc. v. Garlock Inc., 721 F.2d 1540 (Fed. Cir. 1983). Here, Laube does not teach that powdered insulin can be used to help a type I diabetic, who lacks the ability to maintain acceptable blood glucose levels on his own, to achieve acceptable blood glucose levels. While Weiner does suggest inhaling powdered insulin, it explicitly teaches away from the claimed invention by teaching that inhalation of powdered insulin "will not eliminate the need for parenteral insulin therapy in patients with damaged beta cells who do not produce enough insulin to regulate their blood sugar." Col 6, line 1-14. Indeed, all Weiner suggests is that patients on the verge of contracting

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type I diabetes may stop onset of the disease by inhaling or swallowing insulin, if the inhalation or ingestion takes place before beta cell damage has occurred. Thus, even if one were to believe that Weiner discovered a cure for type I diabetes, Weiner's own disclosure shows that he does not have a treatment for treating diabetic patients who have suffered sufficient beta cell destruction such that they cannot regulate their blood sugar on their own. Accordingly, when the references are read together as the Examiner suggests, they—at best—suggest that liquid insulin can be inhaled to lower blood glucose levels and that powdered insulin can stop the onset of type I diabetes if inhaled or ingested before beta cell destruction has progressed. They explicitly teach that powdered insulin inhalation will not eliminate the need to inject insulin in patients with diabetes that are in need of insulin therapy.

The WL Gore case cited above is dispositive. In that case, the Federal Circuit stated clearly and unambiguously that two references cannot be combined to make the claimed subject matter obvious where one reference teaches that a certain material cannot be used in the claimed manner even though the second reference might show that a similar substance can be used in the claimed manner. In particular, in WL Gore, the court noted that one of the reference taught that PTFE could not be handled in the same manner as other plastics. A second reference teaching that plastics could be handled in a certain way, e.g. rapidly stretched, was therefore not amenable to combination with the first reference. In the file history of the present application, the Examiner has cited a reference that says clearly and unambiguously that powdered insulin cannot be used to maintain adequate blood sugar control in diabetics who lack the ability to produce enough insulin on their own. The second reference suggests that liquid insulin can be inhaled and result in some blood glucose lowering affect. Thus, the references expressly teach away from inhaling powdered insulin to treat diabetes.

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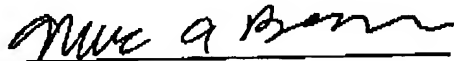
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Inventors: Igor Gonda et al.

### Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early reconsideration of the pending claims is respectfully requested. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Novo Nordisk Inc., Deposit Account No. 14-1447. The Examiner is hereby invited to contact applicants' attorney if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: July 24, 2006

  
Marc A. Began, Reg. No. 48,829  
Novo Nordisk Inc.  
Customer Number 23650  
(609) 987-5800

Use the following customer number for all correspondence regarding this application.

**\*23650\***

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